

Amendment to the Claims:

The claim listing which begins on the next page will replace all prior versions, and listings, of claims in the application.

Claim Listing

1. (Currently amended) A process for the preparation of the α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl]pyrimidin-2-ylamino]phenyl]benzamide comprising:
 - a) carrying out the acid addition reaction using not more than 0.99 equivalents of methanesulfonic acid per 1 equivalent of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl]pyrimidin-2-ylamino]phenyl]benzamide, in a solvent selected from the group consisting of C₂-C₆ aliphatic alcohols and the mixtures thereof, optionally with the addition of a C₁-C₄ aliphatic alcohol;
 - b) adding, if necessary, a solvent selected from the group consisting of the esters of lower carboxylic acids and C₁-C₄ aliphatic alcohols;
 - c) optionally inoculating the reaction mixture with the α -crystal form;
 - d) stirring the reaction mixture for the time necessary for crystallization of the α -crystal form; and
 - e) isolating the α -crystal form from the reaction mixture.
2. (Original) The process according to claim 1 in which the acid addition reaction is carried out using from 0.95 to 0.99 equivalents of methanesulfonic acid per 1 equivalent of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl]pyrimidin-2-ylamino]phenyl]benzamide.
3. (Currently amended) The process according to claim 1, in which the acid addition reaction is carried out in an alcohol selected from the group consisting of *n*-propyl alcohol, isopropyl alcohol, *n*-butyl alcohol, *tert*-butyl alcohol, and the mixtures thereof with ethyl alcohol.
4. (Currently amended) The process according to claim 1, in which the acid addition reaction is carried out in a mixture of solvents containing from 0 to 50% of ethyl alcohol and from 50 to 100% of *n*-propyl alcohol (v/v).

5. (Currently amended) The process according to claim 1 in which the acid addition reaction is carried out in the mixture of solvents containing from 0 to 50% of ethyl alcohol and from 50 to 100% of isopropyl alcohol (v/v).
6. (Currently amended) The process according to claims 1 in which the acid addition reaction is carried out in a mixture of solvents containing from 0 to 50% of ethyl alcohol and from 50 to 100% of n-butyl alcohol.
7. (Currently amended) The process according to claims 1 in which the acid addition reaction is carried out in a mixture of solvents containing from 0 to 50% of ethyl alcohol and from 50 to 100% of *tert*-butyl alcohol.
8. (Currently amended) A process for the preparation of the α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl]pyrimidin-2-ylamino]phenyl]benzamide comprising:
- carrying out the acid addition reaction using 1 equivalent of methanesulfonic acid per 1 equivalent of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino]phenyl]benzamide in the ethyl alcohol, optionally with the addition of a C₁-C₄ aliphatic alcohol;
 - adding a solvent selected from the group consisting of the esters of lower carboxylic acids and C₁-C₄ aliphatic alcohols;
 - inoculating the reaction mixture with the α -crystal form;
 - stirring the reaction mixture for the time necessary for crystallization of the α -crystal form; and
 - isolating the α -crystal form from the reaction mixture.
9. (Currently amended) The process according to claim 8 wherein said C₁-C₄ aliphatic alcohol is methyl alcohol or isopropyl alcohol, and the proportion of said C₁-C₄ aliphatic alcohol to other solvents present in the reaction mixture do not exceed 55% (v/v).

10. (Currently amended) The process according to claim 1 in which the acid addition reaction is carried out with stirring while maintaining the internal temperature of the mixture within the range from room temperature to boiling temperature.

11. (Currently amended) The process according to claim 1 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture is essentially free of the β -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide and any other crystalline solids.

12. (Currently amended) The process according to claim 1 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture shows an X-ray powder diffraction pattern that is characterized by having peaks at 2θ angles of approximately: 4.9; 18.6; 19.1; 23.2 and 28.6°.

13. (Currently amended) The process according to claim 1 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture shows an X-ray powder diffraction pattern that is characterized by having peaks of relative intensity over 20% at 2θ angles of approximately: 10.5; 14.9; 16.5; 17.7; 18.1; 18.6; 19.1; 21.3; 21.6; 22.7; 23.2; 23.8; 24.9; 27.4; 28.0 and 28.6°.

14. (Currently amended) A dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide.

15. (Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide of claim 14 in a crystalline form.

16. (Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide of claim 14 in a crystalline Form I which shows an X-ray powder diffraction pattern that is characterized by having peaks of relative intensity over 20% at 2θ angles of approximately: 16.94, 19.80, 20.08, 20.51, 21.28, 21.65, 21.98, 22.70 and 23.07°.

17. (Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide of claim 14 in a crystalline Form II which shows an X-ray powder diffraction pattern that is characterized by having peaks of relative intensity over 20% at 2θ angles of approximately: 17.23, 17.62, 18.72, 19.90, 20.23, 21.25, 21.59, 22.05, 22.44, 23.38, 23.68, 24.48, 25.41, 26.10 and 28.39°.

18. (Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide of claim 14 in a crystalline Form II according to Claim 17, characteristic in that its X-ray powder diffraction pattern obtained by exposure to CuK α radiation is substantially as depicted in Fig. 9.

19. (Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide of claim 14 consisting of a mixture of the crystalline Form I and Form II which shows an X-ray powder diffraction pattern that is characterized by having peaks of relative intensity over 20% at 2θ angles of approximately: 16.91, 17.60, 18.69, 19.78, 20.50, 21.60, 22.00, 22.70, 23.07, 24.49, 26.13 and 27.25°.

20. (Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide of claim 19, characterized in that its X-ray powder diffraction pattern obtained by exposure to CuK α radiation is substantially as depicted in Fig. 10.

21. (Currently amended) A pharmaceutical composition comprising a dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide selected from the group comprising the crystalline Form I, Form II, and the mixtures thereof; and a pharmaceutically acceptable carriers and/or excipients.
22. (Currently amended) The pharmaceutical composition of claim 21 having an anti-neoplastic activity.
23. (Renumbered 16-2nd, Currently amended) The dimethanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide in a crystalline Form I according to claim 15, characterized in that its X-ray powder diffraction pattern obtained by exposure to CuK α radiation is substantially as depicted in Fig. 8.
24. (New) The process according to claim 2, in which the acid addition reaction is carried out in an alcohol selected from the group comprising *n*-propyl alcohol, isopropyl alcohol, *n*-butyl alcohol, *tert*-butyl alcohol and the mixtures thereof with ethyl alcohol.
25. (New) The process according to claim 2 in which the addition reaction is carried out in the mixture containing from 0 to 50% of ethyl alcohol and from 50 to 100% of *n*-propyl alcohol (v/v).
26. (New) The process according to claim 2 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture is essentially free of the β -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide and any other crystalline solids.

27. (New) The process according to claim 2 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture shows an X-ray powder diffraction pattern that is characterized by having peaks at 2θ angles of approximately: 4.9; 18.6; 19.1; 23.2 and 28.6°.

28. (New) The process according to claims 2 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture shows an X-ray powder diffraction pattern that is characterized by having peaks at 2θ angles of approximately: 10.5; 14.9; 16.5; 17.7; 18.1; 18.6; 19.1; 21.3; 21.6; 22.7; 23.2; 23.8; 24.9; 27.4; 28.0 and 28.6°.

29. (New) The process according to claim 8 in which the acid addition reaction is carried out with stirring while maintaining the internal temperature of the mixture within the range from room temperature to boiling temperature.

30. (New) The process according to claim 8 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture is essentially free of the β -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide and any other crystalline solids.

31. (New) The process according to claim 8 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture shows an X-ray powder diffraction pattern that is characterized by having peaks at 2θ angles of approximately: 4.9; 18.6; 19.1; 23.2 and 28.6°.

32. (New) The process according to claim 8 in which said α -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide isolated from the reaction mixture shows an X-ray powder diffraction pattern that is characterized by having peaks of relative intensity over 20% at 2θ angles of approximately: 10.5; 14.9; 16.5; 17.7; 18.1; 18.6; 19.1; 21.3; 21.6; 22.7; 23.2; 23.8; 24.9; 27.4; 28.0 and 28.6°.